Summer Harvest Adventure: A Garden-based Obesity Prevention Program for Children Residing in Low-resource Communities

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SUMMER HARVEST ADVENTURE: A GARDEN-BASED OBESITY PREVENTION PROGRAM FOR CHILDREN RESIDING IN LOW-RESOURCE COMMUNITIES

1. INTRODUCTION AND OBJECTIVES

1.1 Project Title: Summer Harvest Adventure: A garden-based obesity prevention program for children residing in low-resource communities

Childhood obesity has more than tripled during the past thirty years with 34.2% of children (ages 6-11 years) in dire need of interventions.[1] Even higher incidences of obesity exist among minority and low-resource children where 46.2% of Hispanics and 38.1% of Non-Hispanic black children (ages 6-11 years) are overweight or obese compared to 29.4 % Non-Hispanic whites.[2] As a result, more low-resource children experience higher rates of chronic diseases, social stigmatization, and psychological stress that may affect their social and academic performance.[1,3–7] This disparity in childhood obesity rates creates a compelling and critical call for action that cannot be ignored, especially as progress in obesity prevention among low-resource and racial and ethnic minorities remains limited.[8] Poor diet and physical inactivity contribute to and exacerbate many chronic conditions.[9,10]

The school system and the U.S. Department of Agriculture (USDA), through its school breakfast and lunch programs, provide opportunities for low-resource children to obtain nutritious food and partake in regular physical activity.[11–13] However, millions of low-resource children experience inadequate nutrition because of a reduction in fruit and vegetable intake and reduced physical activity during the summer months when school is not in session. These deficits give rise to food insecurity and rapid weight gain while physical fitness declines.[11,14–16] Thus, interventions addressing these summer deficits are critical as organizations and policy makers work to reduce the childhood obesity epidemic, especially among low-resource and minority audiences.[15–17]

The USDA Summer Food Service Program provides free, healthy meals to children in low-resource areas when school is not in session. In 2014, this important initiative served 160 million meals, but failed to reach over 80% of vulnerable children.[18–20] Low-resource individuals also receive aid from food pantries but too often federal and other programs only reach one in six children and employ a paradigm that focuses on short-term hunger- relief that fails to address systemic food insecurity issues, comprehensive family education, environmental factors, and barriers experienced by low-resource families.[21]

Interventions that address behavioral, social, and environmental strategies in addition to providing access to food are essential in childhood obesity prevention programs. Garden-based learning opportunities for children boost academic achievement, increase acceptance of fruits and vegetables, and improve overall diets.[22–26] The “Great Garden Detective Adventure[27] (GDA)” is a USDA standards-based curriculum administered under its Team Nutrition Initiative[28] that integrates gardening experiences and nutrition education into lessons designed to teach and empower third and fourth graders (ages 8-11 years) to make healthful food choices and develop an awareness of how fruits and vegetables are grown. GDA’s strengths include that it is theory-driven, provides gardening skills training and produce harvesting, and includes healthful food preparation and taste-testing. Based upon Social Cognitive Theory[29] constructs, this program asserts that behavioral change is dependent upon factors environment, people, and behavior.

Yet despite the many benefits of the “Great Garden Detective Adventure,” it has limitations for economically- stressed schools in low-resource communities: 1) it is entirely school-based which leaves a summer gap in education and often, healthy food access; 2) the curriculum is focused predominately on the child in the classroom and the family is not engaged; 3) it requires significant maintenance of a school-based garden (designated outdoor space with adequate sun exposure; soil that is well-drained, lead- and contaminate-free; a continued water source; a safe area that is easily accessible and protected from predators, pet waste, and vandalism; dedicated staff or volunteers to develop, implement, and maintain the garden; continued funding to ensure long-term sustainability, etc.); 4) additional resources are often necessary (eg, Master Gardeners, Junior Master Gardeners, and 4- H clubs) that cause additional scheduling and coordination for teachers; 5) produce varieties are limited (only lettuce, carrots, spinach, chard, beets, and berries recommended); and 6) it lacks family engagement and positive reinforcements as recommended by behavioral scientists.[30]

Our novel intervention, “Summer Harvest Adventure (SHA),” incorporates the strengths of the USDA standards-based GDA curriculum and further enhances it by overlaying:

1. Social Ecological Model (SEM). The SEM is a theoretical construct that views children in the context of their families, communities, and cultures and is recommended as an ideal theoretical framework for obesity prevention programs targeting low-resource and disparate populations, thus providing a strong theoretical base for our intervention.[31–33] Programs developed with a sound theoretical foundation are more effective than those lacking a theoretical base, and the strongest interventions may be built from multiple theories.[34] We will employ both SCT and SEM in our intervention.
2. Group and remote motivational interviewing. The technique of motivational interviewing empowers individuals to set goals that are personally meaningful to them. This is a critical concept for low-resource families who often experience unique barriers related to healthy eating and food access.[4] It is essential to acknowledge the ‘voice’ of our individual participants and support them in positive behavior changes.
3. Family-based social interactions and behavioral reinforcers. These essential components of childhood behavioral interventions are often missing in nutrition education and behavior modification programs.[30] Our novel project includes these components and provides proven, action-oriented strategies that promotes an anti-obesogenic environment for low-resource children and their parents in a positive and fun environment. Specific program components include promoting child-parent/adult caregiver (PAC) interactions in a social setting; behavioral reinforcements and motivational messaging; and weekly fruit, vegetable, and herb harvesting in a community garden. These active ingredients are readily available in many low-resource communities and gaining support nationally.

1.1.1 Preliminary Data

The Summer Harvest Adventure will be part of a larger garden-based initiative supported by The Ohio State University (OSU) land grant resources for vulnerable populations. Our community garden is located on OSU’s main campus at Waterman Farms, a 261-acre living laboratory, devoted to discovering scientifically-proven and evidence-based methods to empower and inform families in achieving optimal health and wellness. Crops are varied and specifically selected to align with local availability and evidence-based dietary guidelines for our target populations. Since its launch in 2012, this garden has been the ‘stage’ in which to provide education, shared kinship, healing, and empowerment to families in need. A summary of our preliminary data are listed below in chronological order:

2013 Pilot. Programmatic surveys and focus groups highlighted numerous advantages reported by participants harvesting at the garden. Our main themes related to improvements in physical and mental health as well as increased socialization providing additional support and motivation. Participants also appreciated the fresh produce, convenient parking, and bus route access reducing transportation barriers.[35]

2014 Pilot. Twenty-two cancer survivors, post active treatment, were observed in a pre- to post-test pilot to assess the feasibility and efficacy of our garden-based intervention over a 4-month period. Participants reported minimal disruption of daily activities and high levels of satisfaction with the intervention. 100% of participants reported that the program helped them achieve positive lifestyle behaviors that were sustained 6-months post- intervention. 100% rated the program as “very good or excellent,” and stated they would recommend the intervention to other populations. Consumption of fruits and vegetables increased ($p=0.003$) while consumption of red and processed meats ($p=0.030$) and sugar-sweetened beverages ($p=0.020$) decreased. Skin carotenoid levels (Fig. 1), fasting blood glucose, and non-HDL cholesterol significantly improved ($p=0.011$, $p=0.043$, $p=0.05$, respectively).[36]

2015 Pilot. The 2014 intervention was repeated with overweight cancer survivors (N=29) for 6 months. Again, we documented significant improvements in fruit and vegetable intake and quality of life, Healthy Eating Index (HEI) scores, body mass index, waist circumference, total cholesterol, blood pressure, skin carotenoids (Fig. 1) and plasma carotenoid concentrations ($p=0.004$; $p=0.006$; $p<0.001$; $p<0.001$; $p=0.008$; $p=0.006$; $p=0.015$; $p=0.003$, respectively). In addition, physical activity increased by 20% over the course of our intervention (Spees, J Acad Nutr Diet, in press).

2016 Pilot. Next, we modified our successful adult intervention to meet the needs of youth, ages 8-11 years, from low-resource communities (defined by school SNAP-eligibility). “Growing Healthy Kids” (see http://go.osu.edu/ghk) is a feasibility pilot that embraces all 3 components of the agricultural knowledge system (extension, education, and research). Within 3 weeks, we successfully recruited and enrolled 30 children/PAC to participate in a 10-week summer pilot. As of this submission, we have proven feasibility, >85% retention, and documented >65% of families actively engaging with our remote motivational interviewing coach (MIC). In sum, the results of our preliminary data prove feasibility, and participants have reported improvements in fruit and vegetable intake and physical activity. Moreover, parents have reported that the program had increased their family’s exposure to new fruits and vegetables, and their children have become adventurous produce eaters.

1.2 Study Rationale

There has been a proliferation of obesity prevention programs that include summer feeding programs.[30] Many of these interventions lack strong behavioral, social, and environmental components aimed at increasing produce intake and physical activity. Indeed, research shows that feeding alone does not change behavior.[1] Promising scientific evidence indicates that family-engaged group activities with behavioral reinforcers (such as targeted motivational interviewing strategies, wireless technologies, and child-PAC components) can lead to positive behavior change.[30] Family interactions and engagement improve when interventions include family activity in a group setting.[12,37–42] Our innovative intervention will focus on addressing the following USDA priorities: 1) develop an efficacious behavioral, social, and environmental intervention to increase dietary intakes of fruits and vegetables; 2) increase physical activity in children; 3) increase the number of parents, caregivers, educators, practitioners, and researchers who receive training and effectively model behaviors necessary to address the complex problem of childhood obesity.

1. Develop an efficacious behavioral, social, and environmental intervention to increase dietary intakes of fruits and vegetables. The majority of childhood obesity prevention programs occur during the academic year when children benefit from federally-funded meals rich in fruits and vegetables.[30] Although there has been modest growth in the federal Summer Nutrition Programs, Ohio ranks in the lowest five performing states for feeding children during the summer months.[18] In Franklin County, Ohio, childhood food insecurity rates exceed 21% (>62,000 children), emphasizing the need for family-based behavioral interventions aimed at promoting healthy summer food access and an anti-obesogenic environment.[43] Family and home environments are essential in the development of food preferences and consumption habits that last a lifetime, yet few options exist for disparate families.[15,44] Certainly, all children can benefit from learning about food: where it originates, safe food preparation, gardening and harvesting skills, and positive health benefits. Research supports: 1) the more children learn about food and nutrition, the likelier they are to consume fruits and vegetables; 2) the more children cook and prepare fresh food, the likelier they are to appreciate healthier and more varied ingredients; and 3) the more children plant and harvest produce, the more motivated they are to eat them.[45–47] Childhood obesity is a multifactorial problem, and families are integral in helping to improve children’s eating habits and prevent obesity. Therefore, engaging parents in the intervention is critical. This trial modifies an existing classroom-based USDA Team Nutrition Program (“Great Garden Detective Adventure”) to address summer food access and modifiable behaviors for families residing in low-resource communities. Our innovative garden-based intervention provides a bountiful harvest of fresh fruit, vegetables, and herbs weekly; we also incorporate key behavioral, social, and environmental strategies as recommended by the scientific community to prevent obesity.[48,49] This unique combination of group education, fresh food access, cooking training, and focused health coaching addresses key barriers to success and challenges the current obesity prevention system.
2. Increase physical activity in children. Dietary intake and physical activity, in combination, improve outcomes in childhood obesity prevention programs.[30] Garden-based programs not only promote increased intakes of fruit and vegetables, but they promote physical activity, thereby improving energy balance. Gardening provides children with moderate to high-intensity physical activity.[50] Our program focuses on improving physical activity for children and families by encouraging physical activity goals, reinforcing physical activity behaviors by providing wearable activity trackers, and supports novel physical activities (harvesting, gardening).

Indeed, our 2015 summer pilot resulted in a 20% increase in physical activity.

3. Increase the number of parents, caregivers, educators, practitioners, and researchers who receive training and effectively model behaviors necessary to address the complex problem of childhood obesity. With strong history of collaborators in extension, nutrition, horticulture, medicine, education, and public health, our team is in a unique position to leverage professional expertise while providing a fully integrative community-based program built upon current theoretical principles and scientific evidence.

   Parents and adult caregivers (PAC) will be fully integrated into SHA and receive training and support in positive behavior modeling, goal-setting, self-monitoring, and behavioral reinforcements. Trained motivational interviewing coaches (MIC) will provide group and individual support to empower families to embrace key obesity prevention strategies and encourage goal-setting surrounding increasing produce intake and physical activity. Child-PAC interactions have historically been absent from obesity prevention programs but are one of the strongest motivators and reinforcers we have to influence behavior change in children.[49]

   Front-line Cooperative Extension educators, dietetic students, and registered dietitians will receive motivational interviewing (MI) training, periodic fidelity checks, and ongoing MI coaching sessions focused on evidence-based MI strategies designed specific to utilizing MI in group settings (extension program assistants) and remote MI strategies (dietitians) targeting low-resource families for promoting prevention of childhood obesity. There are no documented obesity prevention interventions that have adapted core MI techniques and strategies to meet the unique needs of this vulnerable and underserved population. Upon completion, we will have a tested these highly replicable tools and if successful, will disseminate them widely.

   Multidisciplinary undergraduate students will receive college credit (3 semester hours) for participating in a novel “Service-Learning in Vulnerable Communities” course (Health Sciences 2300, Instructor Spees), launched at OSU in Spring 2017. This course examines vulnerable populations from socioecological perspectives including socioeconomic status, ethnicity, culture, mental and physical disabilities, chronic disease, and the impact on both individual and community health. Students will identify implicit biases, participate in poverty simulations, evaluate best-practices designed to meet the needs of disparate populations, compare cultural awareness and cultural competence, engage in respectful, empathetic interactions with low-resource individuals, and engage in experiential service-learning opportunities. Recruitment for this course encourages multidisciplinary undergraduates with interests in education, extension, and community-based research.

   Members of the Advisory and Project Teams include community leaders, parents, educators, practitioners, and students. During the summer of year one, all members of our team will participate in weekly produce harvesting and pre- to post-skin carotenoid assessments. In addition, 10-15 team members will pilot FitBits and track their physical activity patterns. The team will be asked to capture, chronicle, and document their experiences throughout the summer to inform future directions and research questions. These approaches, taken together, were designed to increase the number of individuals and groups trained to address childhood obesity.

1.3 Specific Aims

Aim 1: To examine the efficacy of SHA on change in fruit and vegetable intake from baseline (week 0) to the posttest (week 10) in low-resource children aged 8-11 years.

Hypothesis 1: SHA youths will have greater increases in skin carotenoids from baseline to posttest compared to MSP.

Aim 2: To examine the efficacy of SHA on body composition, physical activity patterns, and obesity-related indices of health after the 10-week intervention.

Hypothesis 2: SHA youths will demonstrate greater improvements in body composition, physical activity, and indices of health post-intervention compared to MSP.

Aim 3: To examine the efficacy of SHA on child-parent/adult caregiver interactions and the

mechanisms of change by which these group differences arise.

Hypothesis 3: SHA youths will demonstrate greater improvements in child-PAC interactions as measured by Expressed Emotion, compared to MSP.

Hypothesis 4: Child-PAC interactions will mediate the improvement in fruit and vegetable intake in SHA compared to the MSP group after controlling for baseline scores.

2. METHODS

2.1 Study Design and Overview

We will conduct a 2-arm RCT designed to determine the efficacy of a multifaceted obesity prevention and lifestyle (diet and physical activity) intervention in low-resource children and parent/adult caregiver (PAC) called "Summer Harvest Adventure." A total of 240 children (ages 8-11 years) will be randomized to the garden-based intervention (SHA) or an enhanced control group, My Summer Plate (MSP). Assessments for both groups will be collected at orientation held one week prior to the intervention (week 0), and immediately following the completion of the intervention (week 10) by trained personnel that are blinded to participants' treatment arm assignment.

2.2 Participant Selection

Any SNAP-eligible adolescent between the ages of 8-11 (as of June 1, for year of enrollment) and his/her parent will be invited to participate in the Summer Harvest Adventure.

2.3 Recruitment, Screening and Informed Consent

This trial will be performed within the OSU land grant university network and will recruit throughout Franklin County, Ohio where the summer meal gaps and food insecurity are prevalent. This RCT will recruit from OSU and Nationwide Children's Hospital's existing community collaborators and established recruitment resources including the public school system, Boys and Girls Clubs, afterschool programs, child care centers, food pantries, federal funded health clinics, public health department, social media, YMCA's, 4-H clubs, and faith-based organizations. We will employ successful recruitment strategies used in obesity prevention interventions for ages 6-11 years.[51] These strategies included passive recruitment (newspaper, radio, flyers, and posters) as well as active recruitment (letters from primary care providers). We are confident our team can recruit 80 families from low-resource communities per intervention cycle (Y2, Y3, Y4). Based upon our pilot data, we expect that approximately 80% of youths will meet the inclusion criteria. We will compare baseline characteristics for all participants that were not approached, those approached who consented, and those approached who did not consent to identify any biases. Although we anticipate more participants than necessary, we will cap our enrollment at the first 80 eligible children/families per year for budgetary reasons.

The study coordinator will contact the family to answer questions, email (or mail) the study assent/consent, and schedule an orientation visit. Any personal health information will be kept confidential and data will only be identified by subject numbers at all stages of the recruitment and assent/consent process. At orientation, the trained study team coordinator will review the assent/consent form by following talking points, asking if participants have any questions, and witnessing participant signing. This includes the signature and the date and time assent/consent was obtained. If an eligible participant's caregiver refuses to provide consent, the study coordinator will discontinue his or her participation.

Enrolled participants will be provided a copy of the signed assent/consent form. The original documents will be filed in a locked study cabinet in a locked office only accessible by the study coordinator and PI. The decision not to partake in this study will not affect a participant's treatment at NCH, OSU, or Extension. Information on participants undergoing the recruitment process but deciding not to partake in the study will be deleted immediately.

2.3.1 Inclusion Criteria

- Children 8-11 years of age (as of June 1, for year of enrollment) from assenting and consenting families

- English-speaking families that agree to participate
- Residents of SNAP-eligible communities in Franklin County, Ohio.

2.3.2 Exclusion Criteria

- Inability to functionally participate in harvesting
- Communication difficulties (e.g. severe developmental delay)
- Lack of transportation to weekly classes or harvesting activities
- Non-English speakers

2.4 Randomization

A web-based randomization and registration process will be designed for the verification of inclusion/exclusion criteria and then randomization of eligible participants. These data will reside behind the OSU firewall for security. All data will be backed up incrementally daily with a full backup weekly. Tracking and error reports will be generated to alert study staff of any data quality issues as they arise. Research staff will follow up on any instances of incomplete or problem data. All baseline and outcome data will be stored electronically in a Research Electronic Data Capture (REDCap) database, which can be accessed only by the approved research staff. Given the nature of the intervention proposed, participants and study staff will know the intervention to which they have been assigned. Therefore, double-blinding will not be possible in this study. For participants that agree to participate in the RCT, the randomization sequence will be based on a randomized design with blocks of size four or six, chosen randomly within the sequence with equal probability. A pseudorandom number generator in the statistical software package R will be used to implement randomization, and the randomization sequence will be maintained by the project statistician and unavailable to other research study members, other than those directly responsible for revealing study group assignment to study participants. This block design assures a balanced allocation to the two intervention groups, and the randomly varying block size reduces the chance that research personnel will be able to guess the next intervention group assignment and thus minimizes any unconscious bias in patient allocation in the RCT. The differing components between each group are described below and in Table 1.

2.5 Intervention

Long-term success in obesity prevention and better health outcomes occur when children receive theory-driven, evidence-based interventions with sustained feedback and support from trained interventionists.[52–54] SHA is a multi-component approach designed to facilitate positive behavior change and promote obesity prevention strategies for families (increase fruit and vegetable intake and physical activity). SHA participants will also receive: 1) weekly remote motivational interviewing coaching (described below); 2) fruit, vegetable, and herb harvesting (in 2-hour blocks); 3) group education classes based on GDA Team Nutrition and promoting MyPlate guidelines[55,56] (delivered by Cooperative Extension educators trained in group motivational interviewing); and 4) healthy food preparation and taste-testing.

The Great Garden Detective Adventure (GDA) is a USDA-supported, standards-based Team Nutrition gardening program for grades 3 and 4 (ages 8 to 11 years) that employs the conceptual tenants of the Social Cognitive Theory (SCT).[27,29,57] The Summer Harvest Adventure enhances and extends the GDA framework and embraces both SCT and the Social Ecological Model (SEM). The SEM is a theoretical construct that views children in the context of their families, communities, and cultures and is recommended as an ideal theoretical framework for obesity prevention programs targeting low-resource and disparate populations.[31,32]

Table 1. Intervention Components between 2 Groups

Individual Components	Enhanced Control Group: My Summer Plate (MSP)	Intervention Group: Summer Harvest Adventure (SHA)
Theoretical model	Social Cognitive Theory	Social Cognitive Theory + Social Ecological Model
Food distribution	None	Fruit, vegetables, and herbs harvested weekly for home preparation and intake
Healthful food	None	Weekly

preparation and taste-testing		
Education	Basic education packet provided at orientation and available online. Education materials focus on USDA MyPlate for Children	10 weekly sessions (60 min each week) with child and parent/adult caregiver held at the garden. Education materials adapted from USDA Team Nutrition's Great Garden Detective Curriculum
Gardening skill training	None	Weekly
Family activities	None	Ongoing (during classes, food preparation, and harvesting, weekly home activities)
Goal-setting and self- monitoring	None	Weekly family-focused remote motivational coaching
Reinforcers	Wearable activity tracker (Fitbit with no visible tracking data available)	Wearable activity tracker (Fitbit with unlimited visible tracking data)
Motivational interviewing and messaging	None	Group and individual (remote) MI during 10 week intervention

2.5.1 Study Orientation

At orientation and after blinded baseline data collection, families randomized to the SHA will receive a FitBit Alta wearable fitness tracker. Participants will be provided verbal and written instructions on how to wear the activity monitor and directions for accessing and synching to a secure web portal. For participants without ready access to Wi-Fi, we will capture weekly quantitative measures and synch data at the garden in a semi- private area. The FitBit Alta has a live tracking display that is visible to participants. This type of device has been shown to serve as a motivator for increasing physical activity patterns.[58–60] In addition, SHA participants will receive a schedule of future classes and harvests and will meet their MIC. At orientation and after blinded baseline data collection, families randomized to the MSP group will receive a FitBit Flex 2 wearable fitness tracker, instructions for use, and obtain an educational packet with MyPlate handouts. This packet will also be available online.

2.5.2 Group Education

Ten group sessions are scheduled for 60 minutes each and will be held at the Waterman Farms classroom adjacent to the garden and will include both child and parent/adult caregiver (PAC) in the lessons. The group education sessions will align with the main components of DGA and MyPlate principles.[55,56] All classes will be led by Cooperative Extension educators trained in group motivational interviewing. Each class will end with healthy food preparation and taste-testings using available garden produce. Families will be encouraged to harvest before and/or after each class. Specific dietary and physical activity components of the intervention phase will be consistent with the MyPlate guidelines for children and include: 1) increasing fruits and vegetables; 2) improving whole grain intake; 3) increasing water intake and limiting sugar-sweetened and high-fat beverages; 4) selecting lean proteins; 5) limiting sweets; and 6) incorporating 60 minutes of physical activity per day. Trained dietetic interns and interdisciplinary service-learning students will be available during all harvests to provide additional assistance and support to families. Again, the MSP group will receive a basic education packet at orientation. Education materials will focus on USDA MyPlate for Children.[55]

2.5.3 Produce Harvesting

For this study, a bountiful harvest of fruits, vegetables, and herbs will be available for 10 weeks. Our 2016 youth garden was rich in variety, color, and phytochemicals (see http://go.osu.edu/ghk). Families can harvest sweet corn, varied squash, purple and white

eggplant, green and rainbow swiss chard, wide varieties of greens and lettuce, red and green basil, multiple kale varieties, cucumbers, zucchini, snap peas, varied peppers, tangerine and cherry tomatoes, garlic, tomatillos, parsley, dill, mint, sage, beefsteak tomatoes, kohlrabi, beets, broccoli, cabbage, numerous berries, apple varieties, melon, and pumpkin. SHA families will each be given a large cloth garden bag and encouraged to harvest a bountiful selection of crops. This produce, for home use, will help fill the summer meal gap for low-resource families and expose them to a wide variety of produce each week. MSP group families will not receive produce harvesting.

2.5.4 Focused Motivational Interviewing Coaching

Those assigned to the SHA group will receive Motivational Interviewing Coaching for the duration of the intervention. Those assigned to the MSP group will not. Motivational interviewing (MI) is a client-centered method for enhancing intrinsic motivation to promote positive health behavior by exploring and resolving ambivalence.[54] Our MIC training is novel in that it will specifically target MI strategies for obesity prevention for low-resource families with children ages 8-11 years. In addition, our MI training will employ precise approaches to encourage child-PAC interactions. Our MI strategies will address families' ambivalence toward behavior change, striving to elicit greater internal motivation to reach obesity prevention goals that are negotiated with families.[49] Our MICs will promote the following modifiable behaviors: 1) improving dietary and physical activity patterns; 2) increasing daily meals and snack structures; 3) reducing screen time; and 4) monitoring behaviors to improve adherence.[48,61,62]

SHA features two MIC approaches during the 10-week intervention: 1) remote individual MIC delivered by trained dietitians and dietetic students and 2) group MIC delivered by trained Cooperative Extension educators:

1. **Remote MIC**. The Commission on Dietetic Registration requires modest MI training as a didactic competency for dietitians-in-training.[63] Unfortunately, this training is highly varied across the nation and primarily focuses on adults with chronic disease delivered within primary care settings. For this project, we will provide focused MI training for dietitians and dietetic students that specifically targets obesity prevention strategies for families residing in low-resource communities and delivered remotely. Our MI consultant conducted ongoing training for our MIC during the 2016 youth pilot (called "Growing Healthy Kids") and conducted validated fidelity measures at two time points (baseline and mid-intervention). The audiotaped and coded encounters between the MIC and PACs showed that our MIC (dietitian) improved in all areas of MI, global MI scores, and met all MI competencies.
2. **Group MIC.** Group MIC interventions are increasing and have been shown to be effective in both adult and youth interventions.[64–68] Our MI consultant will train Cooperative Extension educators to employ MI targeting group-education for families residing in low-resource communities. Our MI consultant will demonstrate how MI principles and processes translate into group contexts, guiding educators to build skills to empower groups successfully.

All MIC's will be trained in rapid identification of the family "nutrition gatekeeper," the individual who acquires and prepares food for the family.[69] Research documents that a child's nutrition gatekeeper (usually mother) has the largest impact on a child's long-term nutrition consumption and controls over 70% of a family's dietary intake.[69,70] MI is highly effective at arming trained interventionists with tools to develop and sustain empathetic and trusting relationships.[54] They will utilize MI strategies to teach the nutrition gatekeepers how to deploy positive reinforcement techniques. Due to the young age of these children, the MIC's will only remotely communicate with the family nutrition gatekeeper or another adult family member. MIC's will also attend weekly group education and harvest sessions to be accessible in-person during these times for both families and children. Motivational interviewing fidelity will be assessed via independent evaluations of randomly-selected audio-taped sessions by an expert MI trainer throughout the study (defined below).

2.5.5 Behavioral Reinforcements

Use of positive reinforcement techniques is a core behavior change strategy for youth obesity prevention.[41,71–73] Praise and child recognition are known key strategies to improve behavior, as well as time spent with PAC and nonfood rewards. This is important, because some PACs reward behavior with food or focus on their children's shortcomings rather than recognizing small successes.[49,70] Parents can reinforce positive obesity prevention strategies through consistent behavior and role-modeling. Reinforcing positive actions improves a child's satisfaction about choices made, which further motivates him/her to improve behaviors that elicits additional perceived rewards.[74,75] In our 2016 Growing Healthy Kids youth pilot, PACs remained fully engaged in the group education and harvest sessions and reported (via de-identified surveys): 1) improved intake of fruits and vegetables for family members at home; 2) greater family engagement related to home meal preparation and tastings; and 3) reinforcement of group education throughout the week. Most astounding is our attendance records document that PACs continue to attend the weekly sessions even when their child is unable to attend.

3. RISKS AND BENEFITS

The risks associated with this protocol are minimal to none. In the case of any adverse events, Dr. Kelly Kelleher from NCH will be notified immediately and the study coordinator will report any serious adverse events to the IRB. Participant confidentiality of records will be maintained. Individuals will not be identified by name or by any other personal identifying information in any data forms, reports, or publications resulting from this study. Thus, risk of disclosure of confidential medical information will be essentially nonexistent.

The benefits regarding participation relative to improving lifestyle behaviors and health outcomes are unknown. The benefits to the scientific community and the public are potentially large. SHA Participants will be provided free garden produce, education, and individual health coaching with motivational interviewing. The MSP goup will receive basic education. Both groups will recieve wearable activity trackers (FitBits). The information gleaned from this study may benefit other adolescents and communities serving SNAP-eligible families in the future. The participants and society in general will benefit from this study to the extent that the results improve our understanding of modifiable lifestyle behaviors as a possible means of preventing childhood obesity and secondary complications. The benefits far outweigh the risks of this study, since the possible risks are considered minimal to none and because the possible benefit is great.

4. MEASUREMENT

Evaluation of program outcomes is essential and will be measured throughout the intervention (Table 2). We anticipate improvements in fruit and vegetable intake, physical activity, and child-PAC engagement. All baseline measures will be taken at the study orientation, one week prior to the start of the 10-week intervention. The information gleaned from this project will be used to inform, educate, and empower families to establish a best practice-based summer obesity prevention model, built upon replicable criteria that can be implemented on a national scale.

Table 2. Procurement and Measures

Variable	Week 0 (Baseline)	Week 10 (Post)
Tracking and Adherence		
Attendance Log	Every class and harvest	
Physical Activity Patterns	X	X
Questionnaires		
Demographics and Health Behaviors Survey	X	X
Expressed Emotion Adjective Checklist	X	X
Program Evaluation		X
Clinical and Anthropometric Procedures		
Body Mass Index Percentile	X	X
Waist Circumference	X	X
Blood Pressure	X	X
Skin Carotenoids	X	X

4.1 Tracking and Adherence

4.1.1 Attendance and Compliance

Attendance at all harvests, group education, and scheduled MIC encounters will be tracked electronically. Participants will receive an attendance card with a unique QR identifier. Each week, participants will present their card to study personnel who will scan it using a mobile scanner. These data will be uploaded into the secure web portal for tracking purposes and for use in 'completer/dosage analyses.' The MICs will monitor weekly attendance and reach out to missing families to encourage continued program participation.

4.1.2 Physical Activity Patterns

Physical Activity Patterns will be assessed using FitBit Alta (SHA group) and FitBit Flex 2 (MSP group). Both wearable devices are 3-axis accelerometer fitness trackers that monitor steps/day and activity minutes. These devices will sync data wirelessly into our secure web portal. They will track seven days of detailed motion data, minute by minute, and daily totals for the past 30 days. The step-counter has been validated against research pedometers and accelerometers.[37,39,58–60] Because Fitbits will be used both for monitoring and incentivizing participants, we have chosen two different FitBit models with different visual display functions. The MSP group will use FitBit Flex 2 and will only be monitored by the study team. They will not receive ongoing physical fitness reports until the study is complete. At that time, they will be given the Fitbit results and allowed to keep the device.

The SHA group will use FitBit Alta and will have real-time and ongoing access to their physical activity data throughout the intervention to track live progress, self-monitor physical activity (steps, active minutes) and assist in goal setting. This device will sync all data wirelessly into our secure web portal and can communicate directly with most smartphones. It tracks seven days of detailed motion data, minute-by-minute and daily totals for past 30 days. Such reinforcements allow individuals to track progress in the form of short-term goals (such as number of steps walked per day) before they reach some longer, more difficult goals (such as changing physical activity patterns). Our MIC will have back-end access to all data and adjust coaching sessions in response to individualized behaviors. Baseline physical fitness patterns will be collected at the study orientation (one week prior to the intervention) to allow for seven days of baseline data capture prior to the intervention.

4.2 Questionnaires

Questionnaires will be collected at baseline (week 0) and post-intervention (week 10). Participants and parents will complete the questionnaires at orientation and end of study at harvest visit or online (via secure web portal). If participants are asked questions that they consider personal or sensitive and pose some psychological risk, they may refrain from responding to those questions. If they do not wish to answer a question, they may choose to select "prefer not to answer" and proceed to the next question. This information will be provided to participants in the instructions for all questionnaires. The study team will send follow-up emails and may call participants who fail to complete the questionnaires within 2 weeks.

4.2.1 Demographics and Health Behaviors

USDA SNAP-Ed surveys will be completed by both child and PAC. The adult survey takes approximately 10 minutes to complete and requests demographics, basic health behaviors, self-efficacy, and lifestyle goals. The youth behavior survey for children (grades 3-5) collects diet and physical activity information and takes approximately 5 minutes to complete.

4.2.2 Expressed Emotion Adjective Checklist

There is national agreement on the critical role that parenting plays in shaping and reinforcing their child's behaviors.[49,76] Child-PAC interactions are not only effective but necessary for long-term behavior change.[41,49,70] Health-related behaviors and patterns are established during childhood and adolescence, and evolve within the context of the family.[33]

Our preliminary data documents garden participants reported improved relationships and social support, two key components for children and families. We will encourage family interaction in all facets of our intervention. We will use the Expressed Emotion Adjective Checklist (EEAC), a brief and sensitive measure to evaluate parent-child interactions.[76–78]

4.2.3 Program Evaluation

Qualitative and quantitative evaluations will be completed at each time point and after all group classes as part of fidelity measurement.

4.3 Clinical and Anthropometric Procedures

4.3.1 Body Mass Index (BMI) Percentile: BMI values are correlated with body fatness and are calculated using weight in kilograms divided by the square of height in meters. Trained research associates, blinded to assignment, will collect pre- and post-measures using standardized CDC youth protocols for height and weight.[79] Participants will be weighed, wearing light clothing and without shoes, on a standardized and calibrated Pro Plus digital scale (Health-o-meter). Weight will be recorded with a precision of 0.1 kg. Standing height will be measured using a standardized fixed stadiometer (Health- o-meter) with a vertical backboard and moveable headboard. Care will be taken to ensure that subjects are standing with feet and chin in proper position for the height measurement. Height will be recorded to the nearest 1 mm with shoes removed. Based on the sex of the child, the correct BMI growth chart will be used (www.cdc.gov). The BMI percentile line closest to that point of intersection is the child's sex- and age-specific BMI percentile.

4.3.2 Waist Circumference: In multivariate regression models, waist circumference is significantly more efficient than BMI in predicting insulin resistance, blood pressure, serum cholesterol levels, and triglyceride levels. Consequently, measurements of waist circumference provide unique predictive information regarding health risks, especially for adolescents. Waist measurements will be completed at baseline and 10 weeks using a tape measure. Waist circumference will be measured with a tape measure at the uppermost lateral border of the hip crest (ilium). Waist circumference will be measured with a precision of 0.1 cm per CDC guidelines for children.[79]

4.3.3 Blood Pressure: BP will be assessed by standard clinical methods using an Omron autocuff. Measurements will all be taken on the right side of the body unless the participant has a cast, amputation, or for some other reason the measurement cannot be taken on the right side.

4.5.2 Skin Carotenoid Score: Resonance Raman spectroscopy (RRS) is a non-invasive, validated method of measuring carotenoid status in skin as a biomarker of fruit and vegetable intake.[80–83] Objective measures of RRS are strongly correlated with serum carotenoid levels and positively associated with estimates of intake from FFQ and automated multiple-pass 24-hour daily recalls among children aged 5 to 17 years. Dietary intakes of produce will be measured using Pharmanex NuSkin Biophotonic Scanner (model S3) using the standardized RSS protocol at baseline (week 0) and post-intervention (week 10).[84] This scan is intended for nutritional purposes and will not be used to diagnose any disease or medical condition. The scan involves passing a safe LED light across the surface of the skin for approximately 2 minutes. 2-3 measures will obtained at each time point.

5. DATA COLLECTION AND MANAGEMENT

All data forms will be created in OSU's REDCap (Research Electronic Data Capture, Vanderbilt University, 2004) electronic data capture tool. REDCap is a secure, web- based application designed to support data capture for research studies, providing: 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for importing data from external sources. The data collected during this pilot will not contain Personal Health Information (PHI). The data will be used for research, not clinical use. Age will be collected but date of birth will not be collected. The study coordinator will maintain all data sheets and online data in REDCap. No data will be sent outside of OSU.

All data sheets and online data will only be identified by the participant number. Data will be stored on secured servers and will only be accessible to the research team assigned to this project. Data sent for analysis will be sent via a secured site.

We will maximize efforts to ensure confidentiality through the use of unique participant numbers. All participants will be assigned a unique project identification number (ID). Participants will be identified throughout the research database by their project ID number. Only the study coordinator and health coach will have simultaneous knowledge of participant identities, ID numbers, and study-related data for all participants in the study. Records and forms will be kept in locked file cabinets in a secured room. Any information stored on the computer is only accessible to study key personnel who have the password to gain entrance into the database. All computer systems will be password-protected against intrusion; all network-based electronic communications of confidential information will be encrypted. Information sent for analysis will not contain any identifiers and will be transmitted in a secure manner. The total time commitment for each participant will be approximately 60 minutes for the orientation. This includes the information session (30 minutes), obtaining informed assent/consent (10 minutes). Questionnaires will take approximately 5 minutes each time (baseline and 10 weeks). All anthropometric procedures (height, weight, waist circumference) will be administered by trained personnel and include anthropometrics (5 minutes), blood pressure (3 minutes) and skin antioxidant measure (5 minutes).

6. STATISTICAL ANALYSES

Power Analysis. To ensure sufficient power is obtained for evaluating SHA compared to MSP, our power analysis is based on our primary hypotheses that SHA will provide a significantly greater increase in skin carotenoids compared to MSP from baseline to post-treatment. We use a Type I error rate of .05 to test this primary hypothesis. For the purposes of examining statistical power, we assume an independent samples t-test is used to test this hypothesis with a minimum of 80% power to obtain a sufficient per group sample size (n), which is assumed equal across groups. Consequently, the standardized mean difference (d) is the effect size required to obtain power and sample size. Note that our primary analysis also allows for the inclusion of a small number of important covariates (e.g., the baseline measure of skin carotenoids), which would generally require an equal to or smaller than that reported here for the same level of statistical power.[85]

The results of our pre-post pilot study for SHA were used as the starting point for estimating the expected effect size for our power analysis.[36] This study demonstrated an effect size of d=0.48 on skin carotenoid pre-post change scores. Because the current study will examine the difference between the SHA and MSP groups, it is also necessary to estimate the expected effect size for the MSP group. In this vein, there is evidence suggesting that skin carotenoids may actually decrease/worsen within the MSP group in this study based on our disparate population and our initial assessment for participants will be immediately following the end of the school year. In particular, a recent study has shown that fruit/vegetable intake for low-income populations is generally lower during the summer months compared to the school year due to the meal gap.[11] These results imply that we may actually expect an effect size larger than 0.48 in this study. However, to be conservative and allow for the possibility that the MSP group may improve as well, for our purposes we assume that change in skin carotenoids in the MSP group will result in an improvement on the order of a small effect of d=1.[86] Taking the effect sizes for each of the SHA and MSP groups together, we would conservatively expect an effect size of d=.38 when comparing these two groups on change in skin carotenoids from baseline to posttest. Table 3 illustrates (a) n for 80% and 90% power and (b) power for n=120, the sample size obtained for our study after accounting for a conservative attrition rate of 20% (initial n of 150, 150 x .80 yields n=120), based on different values for our expected effect size, including our projected effect size of d=.38. As shown, our study has nearly 80% power or more in all illustrated scenarios; in some cases we have close to 90% power or more. Furthermore, for effect sizes of .3 or smaller (near or equal to what are traditionally considered small effects[86]) it may be questionable if such effects are clinically significant, and thus our approach illustrates that we are sufficiently powered for effect sizes reasonably considered to be of clinical benefit in practice.

Table 3. Sample Size and Power for Standardized Mean Difference (δ)

δ	n for 80% power	n for 90% power	Power (%) for n=120
0.50	64	86	97
0.40	100	133	87

0.38	110	147	83
0.35	130	173	77

Data Management. Measures of body composition and health indices will be recorded and entered into REDCap by trained research staff. REDCap will be employed by study staff at OSU to obtain data for self-reported variables obtained from children and families, and these databases will be quality checked and merged to yield a final locked-down database for this RCT. When possible, all data will be collected using electronic forms via REDCap and coded with unique subject numbers. It will be stored on a secure server or in locked cabinets in the lab and will be accessible only to study staff. Consent forms, tracking, and registration of participants will be stored separately from data.

Steps Taken Prior to Conducting Formal Analyses. The primary statistical package used will be SAS, version 9.3. Prior to formal analyses, descriptive analyses will be performed on relevant variables within each group. Data values identified as outliers will be further examined to determine if they are data entry errors, in which case they will be modified when possible. Outliers will generally be kept in the final analysis, unless substantial evidence is available for their deletion. Statistical model assumptions will be examined and appropriate alternatives will be employed when necessary in scenarios where assumptions are violated.

Plan for Handling Drop-outs and Compliance Analysis. Every effort will be made to minimize drop-outs; nevertheless, we realize that it is possible they may still occur. Whenever possible, the reason for withdrawing from the particular treatment arm will be documented. If the family gives consent, we plan to collect as much data as the family will allow with a focus on primary outcomes (e.g., skin carotenoids) for the child, which will be collected at each visit and used in the formal analysis. The drop-out rates will also be determined for each of the two arms in the trial. Also, the number of classes attended will be examined as a measure of compliance. Although not expected, if substantial non-compliance is realized, modern methods for investigating non-compliance will be employed.[87]

Intent-to-Treat Analysis Plan and Plan for Addressing Missing Data. The primary approach for the analyses is intent-to-treat, meaning that individuals will be kept in the group to which they were randomized, regardless of protocol violations or drop-out. Every effort will be made to minimize missing data; yet, missing data may still be realized. If this is so, analyses will be performed to explore plausible missing data mechanisms, and baseline predictors of missingness will be investigated. Furthermore, if substantial missing data is realized, maximum likelihood estimation will be employed where predictor variables associated with missingness will be added to the statistical model. This approach generally provides valid inferences when the missing data mechanism is missing at random[88,89]and is more appropriate than many commonly employed approaches to data imputation.[90]

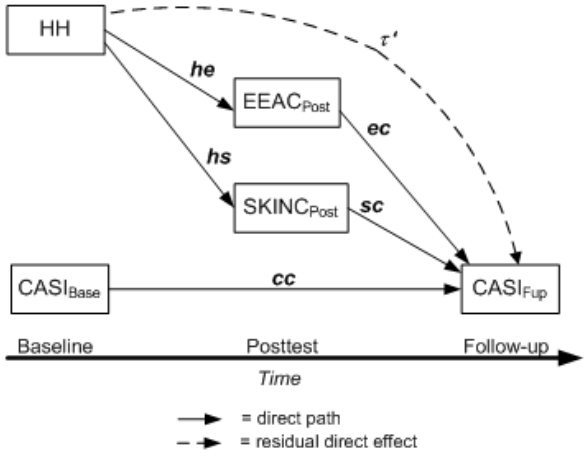
Formal Analysis of Primary Hypothesis. The two groups will be compared on all variables at baseline to determine if statistically significant differences are present using two-sample t-tests or chi-square tests, depending on whether the variable is continuous or categorical. If statistically significant differences are found on baseline measures, they will be examined as covariates in statistical models of interest in an exploratory fashion. Importantly, only the pre-specified covariates of baseline outcome variable, minority status, baseline BMI-z, and cohort status will be included in the primary and secondary analyses.[91] Recall that we are interested in comparing SHA to MSP on pre-post change for our primary analysis. The following statistical model for repeated measures (RM), similar to an ANCOVA but based on maximum likelihood estimation, thus allowing for missing data to be handled appropriately, will be employed,[92] $y_{it} = \boldsymbol{\beta_0} + \boldsymbol{\beta_1 Time_t} + \boldsymbol{\beta_2 Time_t\, x\, Trt_i} + \boldsymbol{\varepsilon_{it}}$, where implicitly it is assumed that there is no main effect of treatment group, $\boldsymbol{Trt_i}$, $\boldsymbol{y_{it}}$ is the skin carotenoid value for child i at time t, $\boldsymbol{Time_t}$ is coded as 0 for the pretest and 1 for the posttest, and the primary effect of interest is $\boldsymbol{\beta_2}$ which corresponds to the difference between the groups on change in child's skin carotenoids. In this model, the baseline measure of child's skin carotenoids is constrained to have equal means across groups by assuming there is no main effect for $\boldsymbol{Trt_i}$. This constraint yields a statistical test for $\boldsymbol{\beta_2}$ analogous to the test of the treatment group main effect in an ANCOVA. The main advantage of the RM model is that it can be estimated in SAS PROC MIXED using maximum likelihood estimation by treating $\boldsymbol{Time_t}$ as a repeated measures factor with two levels, whereas the ANCOVA model would require listwise deletion to account for missing data.

Formal Analysis of our Secondary Hypotheses. The same approach and statistical models employed for

our primary hypothesis will be used for our secondary hypotheses. The main difference between the precise models used will be (a) the specific outcome variable and (b) the time point, posttest or follow-up, employed to form the change score for the hypothesis of interest.

Formal Analysis of Hypotheses 3 and 4. For Hypothesis 3, the same approach and statistical models employed for our primary and secondary hypotheses will be used with the main differences being the outcome variable will be Expressed Emotion. For Hypothesis 4, we will employ a longitudinal mediation model. Specifically, Figure 1 (below) illustrates the model of interest for examining the indirect effects of SHA compared to MSP on the skin carotenoids at the follow-up via the pathway of Expressed Emotion at posttest. The advantages of longitudinal data to examine mediation models have been well-documented in the methodological literature, yielding a unique opportunity for us to test these pathways[74,75,80] longitudinally within an RCT. We will use Mplus 7.31 using the state-of-the-art bootstrapping procedures to statistically test the mediator of interest on the outcome of interest.

Figure 1. Model for Examining Indirect Effects of SHA compared to MSP



7. ETHICAL AND REGULATORY CONSIDERATIONS

Informed Consent: The principles of consent are described by Federal Regulatory Guidelines (Code of Federal Regulations 21 CFR 50) and the Office for Protection from Research Risks Reports: Protection of Human Participants (Code of Federal Regulations 21 CFR 56). They will be followed to comply with FDA and HHS regulations for the conduct and monitoring of clinical investigations. Dr. Spees and her study team will complete the informed consent/assent process. Written informed consent will be obtained before any procedures are performed. This includes the signature and date and time consent was obtained, as indicated by the research subject. The witness signature will be signed where applicable. The participants will not participate in any study procedures until written informed consent has been obtained. The Institutional Review Board and Clinical Trials Office will both receive copies of the informed consent forms.

Institutional Review: This study will be approved by an appropriate review committee as defined by Federal Regulatory Guidelines (Code of Federal Regulations 21 CFR 56) and the Office for the Protection from Research Risks Reports: Protection of Human Participants (Code of Federal Regulations 21 CFR 56). Submission to OSU Institutional Review Board will be completed in a timely manner whereby the protocol, informed consent/assent, and research case report forms will be submitted for review. All IRB documents will be retained by the Principal Investigator and the Clinical Trials Office.

8. HUMAN PARTICIPANTS

8.1 Risk and Benefits

The benefits far outweigh the risks of this study, since the possible risks are considered minimal and the potential health benefits associated with this intervention is great. Potential benefits to the participants will come in the form of increased awareness of food and current guidelines as a means of health promotion. The information gleaned from this study may benefit other adolescents and communities serving SNAP-eligible families in the future. The participants and society in general will benefit from this study to the extent that the results improve our understanding of modifiable lifestyle behaviors as a possible means of preventing obesity, comorbidities and secondary complications of

overweight/obesity. Participants will receive their study results upon request.

8.2 Gender and Ethnic Considerations

Consideration of Special Populations. Cognitively impaired individuals may have difficulty complying with the study requirements and, as such, will not be included in this study. Because access to the garden and the web is critical to this study intervention, prisoners will not be included in this study.

Inclusion of Women and Minorities. This study will be open to non-pregnant women and to all racial and ethnic subgroups without discrimination based upon age or race.

8.3 Data Safety Monitoring Plan

The data and safety monitoring plan will involve the continuous evaluation of safety, data quality and data timeliness. The investigators will conduct continuous review of data and participant safety at their regular weekly group meetings and the discussion will be documented in the minutes. The PI will review outcomes of the trial where applicable at the weekly meetings and determine if the risk/benefit ratio of the trial changes. Frequency and severity of adverse events will be reviewed by the PI and compared to published literature, scientific meetings and discussions with the research team, to determine if the pilot should be terminated before completion. Serious adverse events and responses will also be reviewed by the Data and Safety Monitoring Committee (DSMC). The PI will also submit a progress report (biannually for a pilot study) which will be reviewed by the committee per the DSMC plan. All reportable Serious Adverse Events (SAE) will also be reported to the IRB of record as per the policies of the IRB.

8.4 Protection of Subject Confidentiality

Only study investigators and staff who have completed their institutional or the NIH human participants training will be able to work on this project. Documentation of completion of training will be maintained on file at the project administrative office.

Strict patient confidentiality of records will be maintained. Random numbers will be assigned to each subject and will be used to identify all of that subject's samples and files. Individuals will not be identified by name or by any other personal identifying information in laboratory records, reports, or publications resulting from this study. Thus, risk of disclosure of confidential medical information will be essentially nonexistent. The project team has procedures in place to maintain confidentiality such as password-protected computer access and locked file cabinets and rooms where records are stored, and all team members have received appropriate training. Only the Investigators and study coordinators will have access to any subject data. Access to the data is only possible from specific computers, and data will not be stored on a network. The computers are locked and can only be accessed via an individual password. All personal data will be stored in the secure computers specified above, and in the file cabinet mentioned above. Personal data will be kept at least until publication of results, but in most cases is kept longer in case potential follow- up studies with the same subject will be designed. Typically, personal information will be shredded after 10 years, and all computer files carrying personal identifying data will be erased.

All data sheets and computerized data will only be identified by the subject number. Any further communication with the subject by subject ID will be handled by the PI by cross-checking the subject number with the consent form name and will only be used "as needed" by subject desire for results. Students or staff in the laboratory will not have access to the names of participants associated with any of the data. Data will be compiled by subject number on an excel spreadsheet located on the secure server.

8.5 Suspension of Participation

Participants may voluntarily withdraw from this study at any time without penalty. In such an event, if an enrollee so directs, any relevant data will be destroyed. Participants who drop out of the study for any reason will be replaced with a new subject during the recruitment and enrollment phase. Participants are not obligated to provide a specific rationale for their decision, though a reasonable effort will be made to determine the cause and will be documented since this is a feasibility study.

9. FUTURE DIRECTIONS

The current project focuses on proving the efficacy of SHA aimed at promoting modifiable lifestyle behaviors (diet and physical activity) and improving child-parent/adult caregiver interactions to promote an anti- obesogenic environment for low-resource families. The garden provides a novel setting for testing the efficacy of this comprehensive program, and all of the components are readily available at most land grant universities and in many other communities. A Dissemination Plan will be implemented to communicate key findings and project accomplishments. The dissemination plan will be reviewed periodically by the Advisory and Project Teams. We will emphasize best-practices and contribute to widespread dissemination to inform and encourage professional development of Cooperative Extension educators, students, researchers, and practitioners in other counties in Ohio and throughout the nation. Completion of this study will results in several significant and useful products with immediate impacts.

In sum, the information gleaned from this novel project will be used to inform, educate, and empower providers and families to establish a best practice-based model, based upon quantifiable criteria that can be widely implemented.

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